



Your partner for a safe, strong, and healthy community.

LFA POLICY # 400.125

Douglas Jones

CATEGORY: Administrative Services

EXECUTIVE DIRECTOR

TITLE: Conflict of Interest in Research Activity

DATE REVIEWED: 4/16/2012

POLICY

It is the policy of La Frontera, Inc., that staff have an obligation to maintain the objectivity of their research, avoiding any conflict of interest. A conflict of interest exists when it can be reasonably determined that the personal financial concerns of an investigator or any other person who is responsible for the design, conduct, or reporting of research funded by Public Health Services (PHS), or proposed for such funding could directly and significantly influence the design, conduct, or reporting of sponsored research activities.

This policy complies with specific federal agency requirements laid out in Title 42 Code of Federal Regulations (CFR) Part 50, Subpart F, "Responsibilities of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought."

Every investigator participating in PHS-funded research must comply with 42 CFR Part 50, Subpart F. When La Frontera Center carries out PHS-funded research through subgrantees, contractors, or collaborators, La Frontera Center will take reasonable steps to ensure that investigators working for such entities comply with 42 CFR Part 50, Subpart F, either by requiring those investigators to comply with La Frontera Center's policy or by requiring the entities to provide assurances to La Frontera Center that will enable La Frontera Center to comply with this subpart.

PURPOSE

It is the purpose of this policy to ensure that research activities are conducted for the sole benefit of La Frontera Center, Inc., and not to the benefit of any group or individual within the organization.

PROCEDURE

This policy governing financial conflict of interest applies to all PHS-sponsored investigators of La Frontera Center. The Executive Director is responsible for ensuring implementation of this policy and may suspend all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate by the Executive Director is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to organization policy.

DEFINITIONS

Clinical Trial means any PHS-sponsored research study that involves interaction with human subjects and the concurrent investigative use of drugs, biologics, devices or medical or other clinical procedures, such as surgery.

Family means any member of the investigator's immediate family, specifically, any dependent children and spouse.

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Financial Interest means anything of monetary value received or held by an investigator or an investigator's family, whether or not the value is readily ascertainable, including, but not limited to salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial Interest does NOT include

1. salary, royalties, or other remuneration from the organization;
2. income from the authorship of academic or scholarly works;
3. income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. federal, state, or local governmental agencies; U.S. institutions of higher education; research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
4. equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the investigator does not directly control the investment decisions made in these vehicles.

For investigators, *Financial Interest* also includes any reimbursed or sponsored travel undertaken by the investigator and related to his/her institutional responsibilities. This includes travel that is paid on behalf of the investigator as well as travel that is reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. federal, state, or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Significant Financial Interest means a financial interest that reasonably appears to be related to the investigator's institutional responsibilities, and,

1. if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure, and the value of any equity interest during the 12-month period preceding or as of the date of disclosure, exceeds \$5,000; or
2. if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure exceeds \$5,000; or
3. if with a non-publicly traded company, is an equity interest of any value during the 12-month period preceding or as of the date of disclosure; or
4. is income exceeding \$5,000 related to intellectual property rights and interests not reimbursed through the organization, or
5. is reimbursed or sponsored travel related to their organizational responsibilities.

Financial Conflict of Interest means a significant financial interest (or, where the Executive Director requires disclosure of other financial interests, a financial interest) that the organization reasonably determines could directly and significantly affect the design, conduct, or reporting of PHS-sponsored research.

The *Executive Director* is the individual within the organization that is responsible for the solicitation and review of disclosures of significant financial interests including those of the investigator's family related to the investigator's organizational responsibilities.

Organizational responsibilities means the investigator's professional responsibilities associated with his or her organizational appointment or position, such as research, teaching, clinical activities, administration, and organizational, internal, and external professional committee service.

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Investigator means any individual who is responsible for the design, conduct, or reporting of PHS sponsored research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.

Public Health Service or *PHS* means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

Research means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug).

CONFLICT OF INTEREST

This policy is predicated on the expectation that investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. To that end, this policy informs investigators about situations that generate conflicts of interest related to research, provides mechanisms for investigators and the organization to manage those conflicts of interest that arise, and describes situations that are prohibited. Every investigator has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of interest arises, an investigator should discuss the situation with the Executive Director.

1. DISCLOSURE OF FINANCIAL INTERESTS

All investigators are required to disclose their outside financial interests as defined above to the organization on an annual and on an ad hoc basis, as described below. The Executive Director is responsible for the distribution, receipt, processing, review, and retention of disclosure forms.

a. Annual Disclosures

All investigators must disclose their significant financial interests that are related to the investigator's organizational responsibilities to the organization, through the Executive Director, on an annual basis. All forms should be submitted to the Executive Director or designee by March 1 for the previous calendar year.

b. Ad hoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure. All investigators must disclose their significant financial interests to the organization, through the Executive Director, within 30 days of their initial appointment or employment.

Prior to entering into PHS-sponsored projects or applications for PHS-sponsored projects, where the investigator has a significant financial interest, the investigator must affirm the currency of the annual disclosure or submit to the Executive Director an ad hoc updated disclosure of his or her significant financial interests with the outside entity. The organization will not submit a research proposal unless

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the investigator(s) have submitted such ad hoc disclosures.

In addition, all investigators must submit to the Executive Director an ad hoc disclosure of any significant financial interest they acquire or discover during the course of the year within thirty (30) days of discovering or acquiring the significant financial interest.

c. Travel

Investigators must also disclose reimbursed or sponsored travel related to their organizational responsibilities, as defined above in the definition of financial interest and significant financial interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Executive Director will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a financial conflict of interest with the investigator's research.

2. REVIEW AND DECISION OF THE EXECUTIVE DIRECTOR

If the disclosure form reveals a significant financial interest, it will be reviewed promptly by the Executive Director or designee for a determination of whether it constitutes a financial conflict of interest. If a financial conflict of interest exists, the Executive Director will take action to manage the financial conflict of interest including the reduction or elimination of the conflict, as appropriate.

A financial conflict of interest will exist when the Executive Director or designee determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of PHS-sponsored research. If the Executive Director determines that there is a financial conflict of interest that can be managed, he or she must develop and implement a written management plan. The affected investigator must formally agree to the proposed management strategies and sign the written management plan before any related PHS-sponsored research goes forward.

The Executive Director will periodically review the ongoing activity, monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

3. CLINICAL TRIALS

Review of Significant Financial Interests Related to Clinical Trials

Clinical trials involve particularly sensitive issues if the investigator has a financial interest related to the clinical trial.

In the event of non-compliance with reporting and/or management of a financial conflict of interest involving a PHS-sponsored clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment as required by this policy, the investigator must disclose the financial conflicts of interest in each public presentation of the results of the affected PHS-sponsored research and request an addendum to previously published presentations.

4. REPORTING TO PHS

The Executive Director will report financial conflicts of interest or non-compliance to PHS in accordance with PHS regulations. If the funding for the research is made available from a prime PHS-awardee, such

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reports shall be made to the prime awardee prior to the expenditure of any funds and within 60 days of any subsequently identified financial conflict of interest such that the prime awardee may fulfill their reporting obligations to the PHS.

5. INVESTIGATOR NON-COMPLIANCE

a. Disciplinary Action

In the event of an investigator's failure to comply with this policy, the Executive Director may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Executive Director is implemented.

The Executive Director's decision to impose sanctions on an investigator because of failure to comply with this policy, or failure to comply with the decision of the Executive Director, will be described in a written explanation of the decision to the investigator and, where applicable, the IRB, and will notify the individual of the right to appeal the decision. The organization will promptly notify the PHS awarding component of the action taken or to be taken. If the funding for the research is made available from a prime PHS awardee, such notification shall be made promptly to the prime awardee for reporting to PHS.

b. Retrospective Review

In addition, if the Executive Director determines that a financial conflict of interest was not identified or managed in a timely manner, including but not limited to an investigator's failure to disclose a significant financial interest that is determined to be a financial conflict of interest, or failure by an investigator to materially comply with a management plan for a financial conflict of interest, the Executive Director or designee will complete a retrospective review of the investigator's activities and the PHS-sponsored research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

Documentation of the retrospective review shall include the project number, project title, PI, name of investigator with the financial conflict of interest, name of the entity with which the investigator has the financial conflict of interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The Executive Director will update any previously submitted report to the PHS or the prime PHS-awardee relating to the research, specifying the actions that will be taken to manage the financial conflict of interest going forward. This retrospective review will be completed in the manner and within the time frame established in PHS regulations. If bias is found, the institution will promptly notify the PHS awarding component and submit a mitigation report in accordance with the PHS regulations. The mitigation report will identify elements documented in the retrospective review, a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

6. TRAINING

Each investigator must complete training on this policy, the investigator's responsibilities regarding disclosure, and the PHS regulations prior to engaging in research funded by PHS, and at least every 4 years thereafter. They must also complete training within a reasonable period of time as determined by the Executive Director in the event that this policy is substantively amended in a manner that affects the requirements of investigators, if the investigator is new to the institution, or if it is determined that the

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investigator has not complied with this policy or with a management plan related to their activities.

7. RECORD RETENTION

The Executive Director will retain all disclosure forms, conflict management plans, and related documents for a period of 3 years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee, unless any litigation, claim, financial management review, or audit is started before the expiration of the 3-year period, the records shall be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken.

8. CONFIDENTIALITY

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Institution may be required to make such information available to the PHS awarding component and/or HHS, to a requestor of information concerning financial conflict of interest related to PHS funding or to the primary entity who made the funding available to the organization, if requested or required. If the organization is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the investigator will be informed of this disclosure.

9. PUBLIC ACCESSIBILITY

Prior to the expenditure of funds, the organization will publish on a publicly accessible website or respond to any requestor within 5 business days of the request, information concerning any significant financial interest that meets the following criteria:

- a. The significant financial interest was disclosed and is still held by the senior and key personnel;
- b. A determination has been made that the significant financial interest is related to the PHS-funded research; and
- c. A determination has been made that the significant financial interest is a financial conflict of interest.

The information to be made available shall be consistent with the requirements of the PHS regulation.

10. REGULATORY AUTHORITY

This policy implements the requirements of 42 CFR 50 Subpart F and 45 CFR 94; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.

Disclosure of Financial Interests Report

(Submitted pursuant to the requirements of La Frontera Center’s Conflict of Interest in Research Activity, Policy 400.125)

Name: _____

I am reporting on activities for the year _____
 as an addendum to my most recent report

<input type="checkbox"/> yes	<input type="checkbox"/> no	1. Compensation (including travel expenses). Have you or a member of your family received compensation from a for-profit entity for activities such as consulting, expert witness, advisory board membership, and the like? If yes, furnish information on an additional page.
<input type="checkbox"/> yes	<input type="checkbox"/> no	2. Equity. Do you or a member of your family own stock or hold stock options with a publicly traded or privately owned entity? If yes, furnish information on an additional page.
<input type="checkbox"/> yes	<input type="checkbox"/> no	3. Role. Do you or a member of your family serve as a director, trustee, officer, or other key employee in a for-profit corporation, partnership, business, or other entity outside of La Frontera Center? If yes, furnish information on an additional page.
<input type="checkbox"/> yes	<input type="checkbox"/> no	4. Intellectual Property. Do you or a member of your family have rights to and/or receive royalties from intellectual property (including patents, copyrights, and trademarks but excluding academic or scholarly works) licensed to and/or owned by a for-profit entity? Do NOT include intellectual property owned or managed by La Frontera Center. If yes, furnish information on an additional page.

Certification:

I have read and understand the La Frontera Center’s policy on Conflict of Interest in PHS Funded Projects and have completed this report to the best of my knowledge and belief. If required, I will comply with any conditions or restrictions imposed by La Frontera Center to manage any real or perceived conflicts. Should my outside financial or managerial interests, or those of my family, change in a way that results in different answers to any of the questions asked in this report, I agree to submit a revision.

Signature

Date

Additional page(s) attached.



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Addition to Disclosure of Financial Interests Report of _____

Reporting for self family member:
Name: _____
Relationship: _____

Name of external entity: _____
Address of external entity: _____

Type of external relationship (Check all that apply):

<input type="checkbox"/>	Consultant
<input type="checkbox"/>	Speaker
<input type="checkbox"/>	Advisory Board or Committee
<input type="checkbox"/>	Equity Holdings
<input type="checkbox"/>	Governing Board or Officer
<input type="checkbox"/>	Intellectual Property Rights
<input type="checkbox"/>	Royalty Income
<input type="checkbox"/>	Other (describe below)

Amount of compensation or financial interest in reporting period: _____ \$

If travel paid by entity:
Destination: _____
Amount: \$ _____

Comments or explanatory information: